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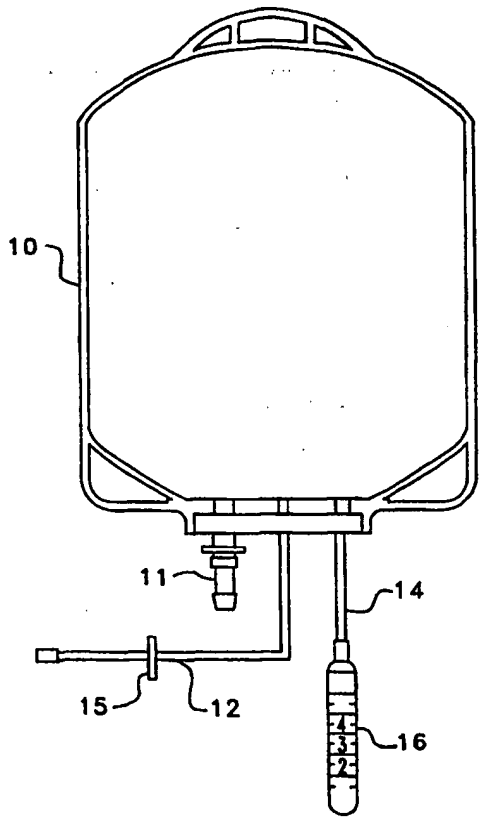
(54) Title: APPARATUS AND METHOD FOR BLOOD COMPONENT SAMPLING

(57) Abstract

A collection system for bodily fluids that includes a collection bag (10) and a sample bulb (16) attached to the collection bag (10). The sample bulb (16) is a one piece element blow molded of material flexible enough to be hand compressed to fill the bulb (16). The method of forming the sample bulb (16) by blow molding polymer material is also provided. The shape of the sample bulb (16) is important in maintaining a constant platelet concentration.



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APPARATUS AND METHOD FOR BLOOD COMPONENT SAMPLING

FIELD OF THE INVENTION

The present invention relates to a device for sampling biological fluids. More particularly, the invention relates to a device for sampling collected blood or blood components that is easy to fill with the collected blood or component and is sized to allow for subsequent testing of the blood or blood component in the sample device itself.

BACKGROUND OF THE INVENTIONS

Often, for various medical related procedures, it is necessary to collect bodily fluids. More particular, it is often necessary to collect blood or blood components such as platelets. The collection of blood components typically occurs during an apheresis process such as that described in U.S. Patent No. 5,653,887. Frequently the collected blood or blood components are collected into collection bags for later use or re-infusion. It is often necessary to sample the collected product to determine product cellular concentrations, product viability, blood typing or other factors while maintaining a closed system.

Various methods have been used to sample blood components collected into bags. One method comprises mixing the bag contents, and sealing and stripping the inlet tubing to the bag to procure a sample in a tube segment. Also multiple tube segments have been sealed to achieve a number of samples. A problem with these methods are that they are not fully representative of the total product in the collection bag but rather the sample is mixed with residual product in the inlet collection tubing. Therefore, it is at best only an approximation of the final end product. Also, the multiple tube stripping operations are considered unsafe by many as broken tubes can splatter blood.

Sample containers have also been bonded to or welded onto collection bags. Such sample containers have been made of semi-flexible tubing material sealed at one end to form a wedge shaped bottom. The inconsistent internal geometry of the tubing makes it difficult to place accurate volume markings on the container. Such

sample containers of tubing material are generally larger in diameter than the tubing that connects them to the bag. Also, another problem with some of these prior art sample containers are that they are not sufficiently flexible to allow hand compression and therefore are difficult to fill with the requisite amount of the component or material to be sampled. The relative rigidity of the container prevents proper compression of the container to displace air and to allow the container to fill with the fluid to be sampled. Such sample containers also generally require several bond locations for the attachment and construction, and solvent bonding is expensive. Another problem with these containers is that for 2-4 ml samples, platelets are more likely to adhere to their wedge shape bottom portion.

Collection bottles have also been previously used. Such bottles sometimes contain a sample container or vial sealed to the top of the bottle by a sample tube. A representative amount of material is decanted from the bottle into the sample vial. With a collection bottle it is necessary to tilt the bottle to transfer liquid through the sample tube and to fill the sample vial. It is further necessary to provide a vent in the sample vial to vent air. The vent can be a source of contamination unless a suitable filter is used.

SUMMARY OF THE INVENTION

Accordingly, it is an object of the present invention to provide a sampler or sample bulb that does not require a vent filter.

It is also an object of the instant invention to provide a sample bulb that can be hand compressed to assure proper filling of the required known amount for a sample collection.

It is a further object of the present invention to provide a sampler that is easy and inexpensive to manufacture and that requires few bond joints for attachment to the collection bag.

An additional object of the invention is to provide a sample bulb that has a shape that best preserves product viability for subsequent testing.

It is a further object of the invention to provide a sample method that minimizes disturbances of the product to be sampled to assure accurate testing or analysis.

The instant invention provides a collection system for bodily fluids that includes a collection bag, and a sample bulb attached to the collection bag. The sample bulb is a one piece element blow molded of material flexible enough to be hand compressed to fill the bulb.

The invention further provides a one piece, blow molded sample bulb flexible enough to be hand compressed and the method of forming the sample bulb by blow molding polymer material.

Also provided is a method of providing a sample for analysis that includes hand compressing a sample bulb to fill the bulb with the sample and severing and sealing the filled sample bulb.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is an elevation view of a sample device including a collection bag in accordance with the instant invention.

Figure 2 is an elevation view of a sampling bulb in accordance with the instant invention.

Figure 3 is an elevation view of a severed or cut sample bulb with stopper removed in accordance with the instant invention.

Figure 4 is a chart indicating the platelet sample contact area.

Figure 5a is a schematic showing the dimensions of a cylinder used to calculate the contact area as depicted by line 1 of Figure 4.

Figure 5b is a schematic showing the dimensions of the sample bulb of the instant invention used to calculate the contact area as depicted by line 2 of Figure 4.

Figure 5c is a schematic showing the dimensions of a wedge bottom sample container used to calculate the contact area as depicted by line 3 of Figure 4.

Figures 5d and 5e are schematics showing the dimensions of a horizontal

cylinder sample container used to calculate the contact area as depicted by line 4 of Figure 4.

Figure 6 is a schematic view of typical analysis equipment used for analyzing blood components.

Figure 7 is a partial cross-sectional view of the molding apparatus and parison for molding the sample bulb. The mold is shown in cross-section.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The instant invention is used to sample and analyze bodily fluids and more preferably to sample and analyze blood components. Such blood components are separated from whole blood through an apheresis system such as that shown in U.S. Patent No. 5,676,644. It is understood, however, that another type of separation system could be used. It is also understood that the instant invention could be used to sample whole blood or to sample other body fluids that have not been separated.

The instant invention can be used to sample platelet product that will be later reinfused to a patient. All apheresis platelet products are sampled to determine the concentration of platelets in the collection. Such concentration is important in determining the amount of platelet product to be reinfused.

It is understood, however that the instant invention can be used to sample other bodily fluids for cell count, blood type, or other factors or characteristics. Figure 1 illustrates the preferred sampling device of the instant invention. A collection bag 10 is provided. Typically, the collection bag 10 is formed by welding, (by radio frequency (RF), heat, or other well known methods), two pieces of polymer material together. It is understood that the shape of the collection bag 10 can vary and Figure 1 is only one representative type of known collection bag.

During the welding process used to form the bags, an access site 11, inlet tubing 12 and sample tubing 14 can also be welded to the bag. For the bag shown in Figure 1, such features are directly attached during the bag construction process.

It is understood that radio frequency or RF welding is preferred for the bag construction and attachment of the various tubing and access sites. It is also understood that such tubing and access sites can be attached by bonding or other well known heat or welding techniques.

Only one collection bag 10 is shown in Figure 1, however more than one bag can be used for a component collection. Such bags generally have a Y-shaped port, (not shown), connecting the inlet tubing 12.

In Figure 1, inlet tubing 12 is shown connected to the bag. The component to be collected enters the collection bag 10 through the inlet tubing 12. Slide clamp 15 is used to close the inlet tubing when sufficient product has been collected. Product can subsequently be diverted to other collection bags, (not shown), if sample testing shows sufficient platelets to split into two or more transfusable doses of platelets.

A sample bulb 16 in accordance with the instant invention is directly connected to sample tubing 14. Such sample bulb will be described more particularly below. The sample bulb 16 can be connected to the sample tubing 14 directly by bonding. It is understood, however, that other well known attachment methods can be used. It is also understood that the sample bulb and the connection tubing required, if any, can be a one piece element with such element being connected to the collection bag by welding or other known methods. The apparatus shown in Figure 1 requires only one bond to attach the sample bulb to the collection bag as the sample tubing is connected to the bag by welding.

After collection of a sample it is necessary to separate collection bag 10 from sample bulb 16. It is understood that sample tubing 14 can be closed and severed to seal collection bag 10 and sample bulb 16 from each other by many methods. One preferred method is to close the tubing 14 by grommets or clamps, (not shown), and to manually cut the tubing 14 between the grommets or clamps. Other well known methods, such as the use of an insulated sleeve more fully described in U.S. Patent No. 5,496,301 and U.S. Patent No. 5,345,875 and an RF tubing sealer of the type described in U.S. Patent No. 4,130,860 could also be used.

The sample bulb 16 will be more fully described with reference to Figure 2. The sample bulb is formed as a one-piece element of blow molded construction and the blow molding process will be more fully described later with reference to Figure 7.

The sample bulb has a first opened end 21 and a second hemispherical bottom end 22. The main body portion 26 forms a right circular cylinder, that is, a cylinder with a circular cross-section. The main body portion 26 has a slightly narrowed portion 27 as will be more fully described later. The main body portion 26 along with the hemispherical bottom end 22 approximates a test tube in overall shape. The main body portion 26 is provided with indicia 23 that can be used to indicate the fluid amount in the bulb. Such indicia 23 are marked on the bulb after compensation for the thickness of the bulb material to accurately reflect the contained fluid amount. It is preferable that the bulb accommodate at least 5 ml of fluid.

Although in the preferred embodiment the bulb has hemispherical bottom end, it is also understood the bulb could have a flat end so that the bulb generally approximates a cylinder having a flat bottom or the bottom end could be conical.

In the preferred embodiment the bulb preferably has a length of approximately 3.07 inches to its outside wall. The main body portion has a radius of approximately .250 inches to its outside wall with the narrowed portion 27 having a slightly smaller radius. The radius of end portion 21 is approximately .13 inches to it's outside wall and is smaller than the radius of the main body portion. It is understood these dimensions can be varied to provide the needed sample for the requisite testing and to accommodate standard size constraints. It is preferable that the bulb be sized to accommodate standard test tube racks and standard laboratory equipment.

The shape of the sample bulb is important in maintaining a constant platelet concentration to assure accurate testing. Activated platelets have a tendency to adhere to non platelet surfaces as well as each other. The less contact surface area presented by a sample container per volume the fewer the number of platelets that

will be able to adhere to its internal surface. The adhered platelets generally cannot be counted as part of the overall platelet concentration. Therefore, it is desirable to minimize the surface area of contact per volume to assure a greater and more accurate concentration count.

The chart of Figure 4 graphs the area of contact (cm^2) per sample volume (ml) for four types of sample containers.

Line 1 represents a flat bottom cylinder. For such a cylinder the following equation was used to calculate the surface area of contact:

$$\frac{Samplevolume}{surfaceareaofcontact} = \frac{V_s}{S_{ac}} = \frac{H}{1+\left(4H/d\right)}$$

wherein, as shown in Figure 5a, d is the diameter of the cylinder and H is the height of the cylinder.

Line 2 represents the configuration of the sample bulb of the instant invention; that is, a right circular cylinder having a hemispherical bottom. The following equation was used to calculate the sample contact area of the sample bulb:

$$\frac{Samplevolume}{surfaceareaofcontact} = \frac{V_s}{S_{ac}} = \frac{d+3dH}{6d+12H}$$

wherein, as shown in Figure 5b, H is the length of the right circular cylinder above the hemispherical bottom and d is the diameter of the cylinder.

Line 3 represents the prior art semi-flexible tubing material container having a wedge shaped bottom. For calculating the surface area of contact of the wedge bottom cylinder the following equation was used.

$$\frac{Samplevolume}{surfaceareaofcontact} = \frac{V_s}{S_{ac}} = \frac{d^2}{6.62d+2.31\pi} + \frac{\pi Hd}{11.46d+4\pi H}$$

wherein, as shown in Figure 5c, d is the diameter of the cylinder and H is the height of the cylinder excluding the wedge bottom.

Line 4 represents a horizontal cylinder or the cylinder represented in line 2 on its side as is frequently done for shipping and storage. The following equation was used to calculate the surface of contact area:

$$\frac{Samplevolume}{surfaceareaofcontact} = \frac{V_s}{S_{ac}} = \frac{\left(\frac{\pi A}{180}\right) - (SinA)}{\frac{\pi A}{d45} + \frac{2}{L}\left(\frac{\pi A}{180} - SinA\right)}$$

wherein, as shown in Figures 5d and 5e, 2 lines drawn from the center of the cylinder to the edges of the volume contained therein are at an angle A to each other and d is the diameter of the cylinder and L is its length.

Figure 4 shows that the sample bulb on the instant invention presented less area of contact than the other configurations, except for the horizontal cylinder, with a volume of approximately 2.8 to 4.5ml. The sample bulb of the instant invention clearly presented less area of contact than the prior art sample container having the wedge shaped bottom.

The method of manufacturing the sample bulb will now be more fully described with respect to Figure 5. The bulb 16 is blow molded of a polymer material. The preferred material is polyvinylchloride (PVC) but it is understood that other polymer materials, including but not limited to polyethylene and polyurethane could be used.

For accurate analysis the polymer material selected should not adversely react with the fluid to be sampled.

In the preferred embodiment the sample bulb 16 is blow molded by an extrusion blow molding technique. In extrusion blow molding the melted polymer is extruded by known techniques as a tube into the air. This tube or parison is shown at 41 in Figure 5. The hot parison 41 is captured by two mold halves 42 and 43 having the appropriately shaped mold surfaces 44 and 45. The mold halves 42 and 43 are closed, (by clamps or other known mechanical methods, not shown), and heated. Compressed air is inserted into the parison through blow pin 46. The compressed air expands and inflates the parison against the relatively cold mold surfaces 44 and 45 to shape the hollow sample bulb.

The extrusion and molding can be continuous or intermittent as is well known. It is also understood that other well known blow molding techniques such as injection blow molding or stretch blow molding could also be used.

In the preferred embodiment the thickness of the walls of the sample bulb can vary from .005 inches to .1 inches but the walls of the bulb should preferably be thin and flexible enough to allow hand compression as is more fully described below.

For testing or analysis of the product collected in the sample bulb it may be necessary to severe the open end 21 at or about area 24, (shown in Figure 3), from the main body portion of the sample bulb. The shape of the narrowed area or portion 27 of the main body portion 26 provides for the use of a stopper 25 if needed. The area 27 is sized to accommodate a standard stopper 25. Such stoppers are typically sized to accommodate standard test tubes and such available stoppers can be used with the sample bulb 16 of the instant invention. Such stoppers can be pierced if needed for additional samples.

It is noted that the sample product can generally be analyzed in the sample bulb without transfer to a different container. This prevents damage to the sample from the transfer and generally assures more accurate testing results.

A typical machine for analyzing whole blood or blood components is shown at 3 in Figure 4. One such machine is a Baker 9173 cell counter, manufactured by BIOCHEM IMMUNOSYSTEMS, Inc., 100 Cascade Drive, Allentown, Pennsylvania 18103-9562 but it is understood that other analyzers can also be used. Such analyzers have various controls 32 to achieve the desired functions. The cell counter 31 analyzes product that is contained in sample bulb 36. The sample bulb is formed and used in accordance with the instant invention. The sample port 33 is capable of being inserted into sample bulb 36. A probe (not shown) extends into the fluid contained in the inserted bulb 36 to perform the necessary analysis.

It is understood that Figure 4 illustrates only one example of an analyzer that accepts sample bulbs. Any analyzer that accepts test tubes can accept sample bulbs of the instant invention.

The sampling operation will now be described more particularly with reference to Figures 1, 3 and 4.

After a blood component, whole blood, or a bodily fluid is collected into bag 10, slide clamp 15 is closed. If desired, the contents of the collection bag may then be gently mixed.

Sample bulb 16 is then hand compressed to force air out of the bulb 16 and to allow a small amount of the contents of the collection bag to enter sample bulb 16 to the requisite level. The ease with which the sample bulb can be hand compressed allows for a sufficient amount to be collected for testing. The sample tubing 14 is then sealed and severed to separate the collection bag 10 from the sample bulb 16. The bulb 16 containing the sample is then transported for testing.

At the lab the bulb is severed at 24 if needed and attached to the desired analyzer. The shape of the bulb allows the product to be tested while it is still contained in the bulb.

Alternately, a stopper can be inserted so that the product may be stored. The stopper 25 can be pierced for additional samples.

It is understood that the sample bulb can be retained in its original shape for testing and may not need to be severed as shown in Figure 4. It is also understood that the sample product can be transferred to another container for testing if required by the particular analysis machine.

Obviously, many modifications and variations of the present invention are possible and will be evident to those of ordinary skill in the art. It is therefore to be understood that within the scope of the appended claims, the invention may be practiced in ways other than as specifically described herein.

WHAT IS CLAIMED:

1. A collection system for bodily fluids comprising:

a collection bag;

a sample bulb connected to the collection bag at a first end;

said sample bulb comprising:

a one piece element blow molded of material flexible enough to be hand

compressed to fill the bulb with the desired amount of fluid from the collection bag.

2. The collection system of Claim 1 wherein said one piece element comprises a main body portion having a generally right circular cylindrical shape and a hemispherical bottom at a second end opposite said first end.

3. The collection system of Claim 2 wherein said sample bulb is configured approximately in the shape of a test tube; and

said sample bulb is capable of being accommodated in apparatus that accommodates test tubes.

4. The collection system of Claim 2 wherein said main body portion has a cross section radius of approximately 0.25 inches to the outer wall of the sample bulb.

5. The collection system of Claim 1 wherein said blow molded material comprises a polymer material.

6. The collection system of Claim 5 wherein said polymer material comprises polyvinyl chloride.

7. The collection system of Claim 5 wherein said material is of a thickness in a range from .005 inches to .1 inches to allow the sample bulb to be filled by hand compression.

8. The collection system of Claim 1 wherein said sample bulb is sized to accommodate approximately 5 ml of bodily fluid.

9. The collection system of Claim 1 wherein the bodily fluid is a platelet product and the sample bulb is sized to accommodate approximately 5 ml of platelet product.

10. A sample bulb comprising a one-piece blow molded element having a generally right circular cylindrical shaped main body portion, said element being formed of flexible blow molded material to allow hand compression of the bulb to fill the bulb.

11. The sample bulb of Claim 10 wherein the flexible material comprises polymer material.

12. The sample bulb of Claim 10 wherein the sample bulb is sized to accommodate 5 ml.

13. The sample bulb of Claim 10 wherein the bulb has a hemispherical bottom and a shape that approximates a standard test tube and the bulb is capable of being accommodated in apparatus that accommodates test tubes.

14 The sample bulb of Claim 10 wherein the flexible material is of a thickness in the range from .005 inches to .1 inches to allow the sample bulb to be filled by hand compression.

15. The sample bulb of Claim 13 wherein said main body portion has a circular cross-section having a radius of approximately 0.25 inches to the outer wall of the sample bulb.

16. The sample bulb of Claim 10 further comprising indicia markings on the bulb wherein said bulb can be hand compressed to fill the bulb to the desired indicia marking.

17. The sample bulb of Claim 13 wherein said bulb comprises an open end opposite said hemispherical bottom, said open end having a smaller radius in cross-section than that of said main body portion.

18. The sample bulb of Claim 10 wherein the interior surface of said bulb is shaped to minimize the contact area between the interior surface of the bulb and any fluid contained therein.

19. A method of forming a one-piece sample bulb comprising:

forming a mold cavity having an open end, generally right circular cylindrical sides and a rounded end opposite the open end;

inserting a hot parison of polymer material into the mold cavity;

forcing heated air into the parison of polymer material in the mold to expand the polymer material into a hollow sample bulb shaped by the mold.

20. The method of Claim 19 wherein said polymer material comprises polyvinyl chloride.

21. A method of providing a sample for analysis wherein the sample is taken from a blood component collection bag containing a blood component to be sampled comprising:

hand compressing a sample bulb attached to the blood component collection bag to fill the sample bulb from the blood component collection bag with the desired amount of blood component to be sampled;

sealing the sample bulb;

severing the sample bulb from the collection bag.

22. The method of Claim 21 further comprising:

placing the severed sample bulb in analysis apparatus;

analyzing the blood component contained in the sample bulb with the analysis apparatus.

23. The method of Claim 21 further comprising cutting one end of the sample bulb to form a sample bulb that approximates the shape of a test tube.

24. The method of Claim 23 further comprising closing the cut end of the sample bulb with a stopper.

25. The method of Claim 21 wherein the step of hand compressing further comprises:

hand compressing the bulb to fill the bulb with approximately 2 to 5 ml of blood component.

26. The method of 21 wherein the blood component is a platelet product and the step of hand compressing comprises filling the sample bulb with the desired amount of platelet product.

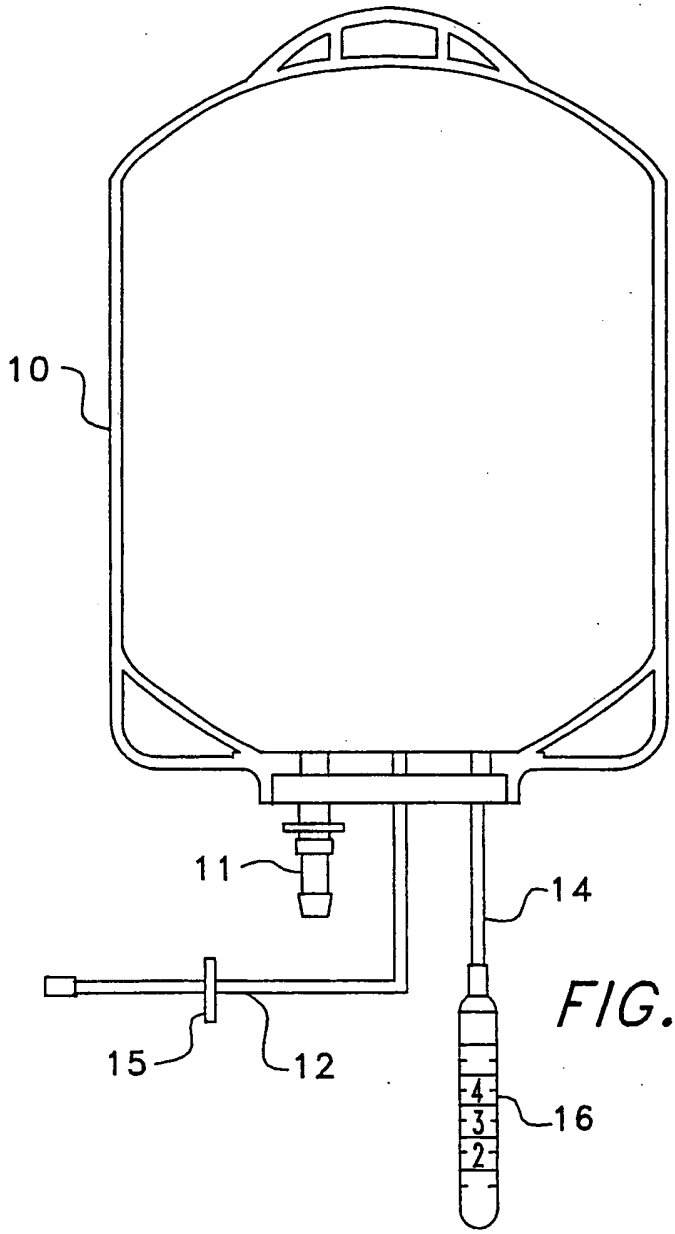

FIG. 1

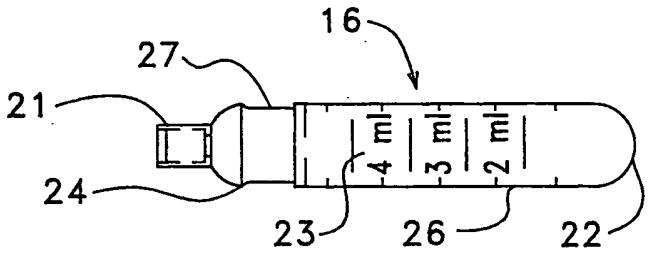

FIG. 2

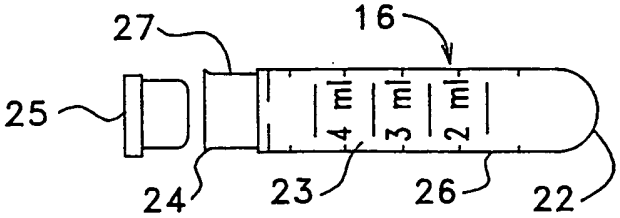

FIG. 3

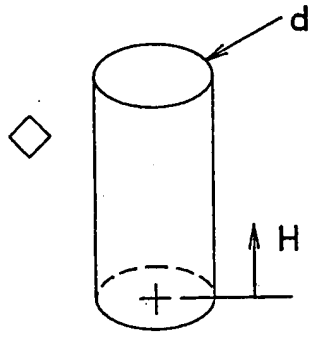

FIG.5a

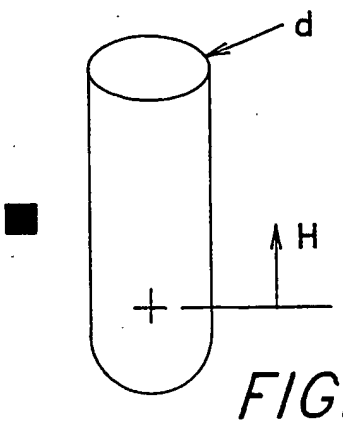

FIG.5b

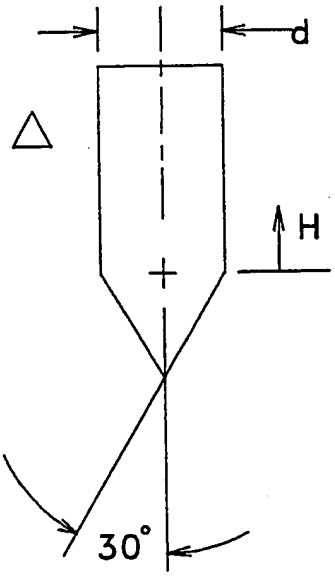

FIG.5c

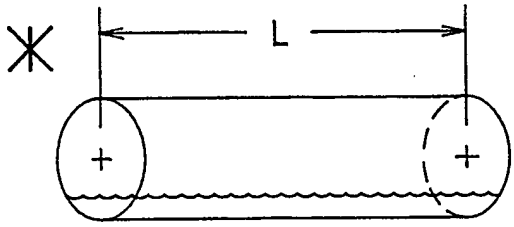

FIG.5d

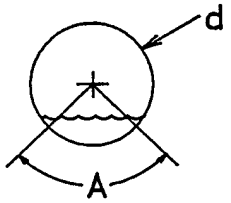

FIG.5e

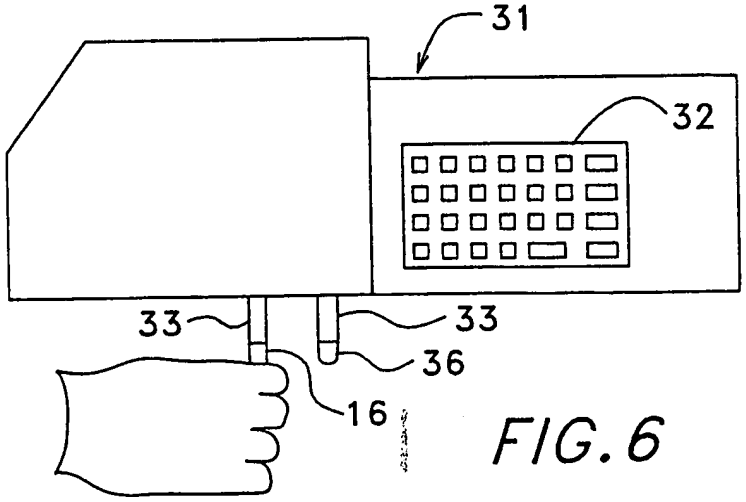

FIG.6

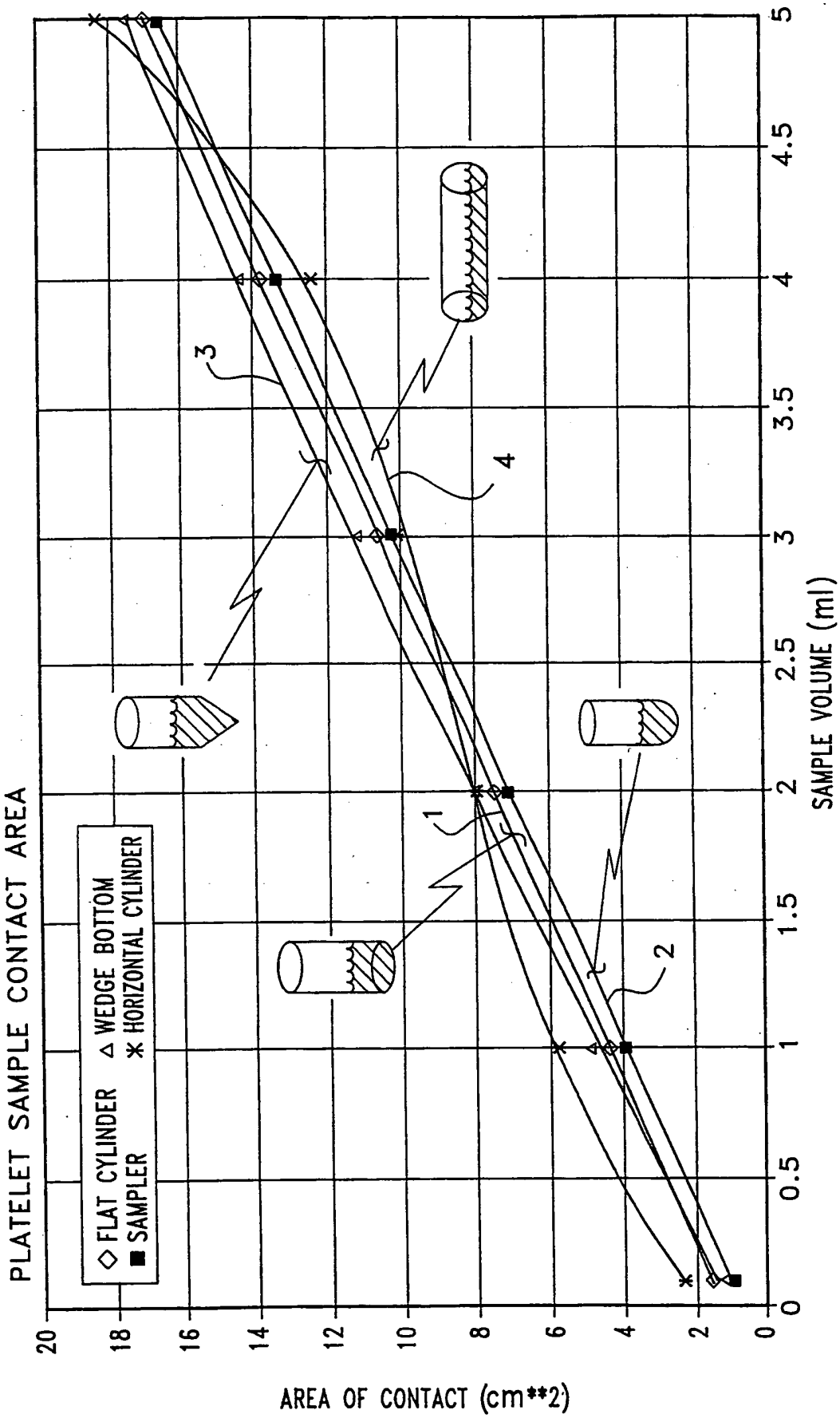

FIG. 4

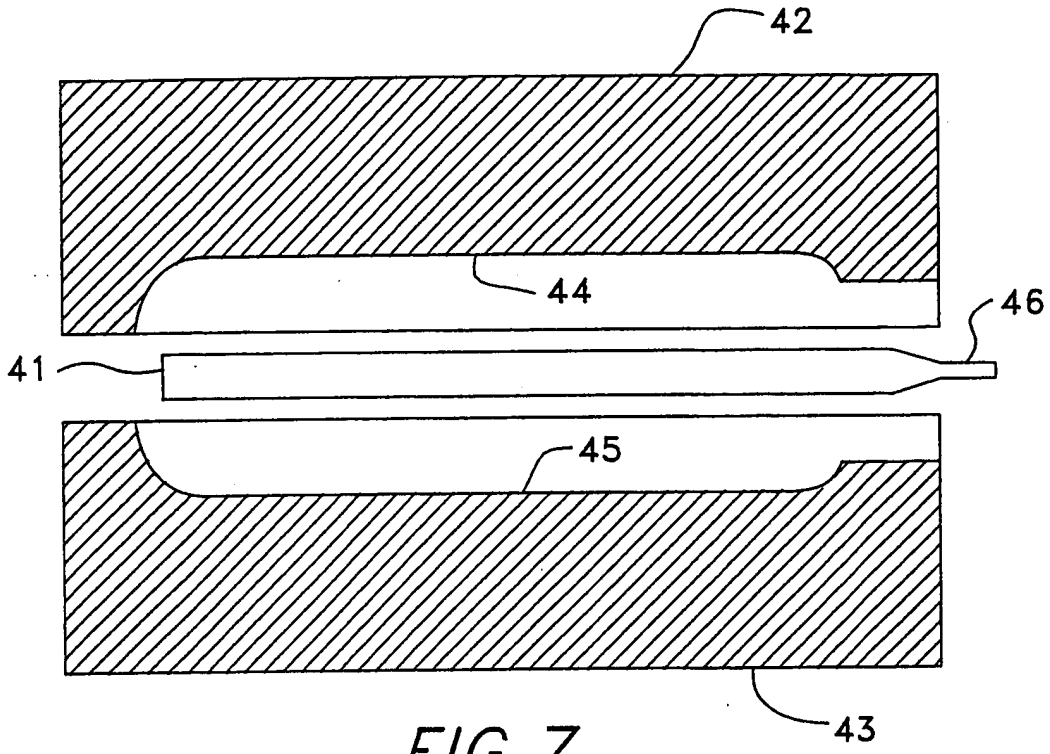

FIG. 7